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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MALLINCKRODT LLC, MALLINCKRODT INC. and DEPOMED, INC. Plaintiffs, v. ACTAVIS LABORATORIES FL, INC. Defendant.	Civil Action No. 15-3800 (KSH)(CLW) **ANSWER OF PLAINTIFFS MALLINCKRODT LLC, MALLINCKRODT INC., AND DEPOMED, INC. TO DEFENDANT ACTAVIS LABORATORIES FL, INC.'S AMENDED COUNTERCLAIMS**

Plaintiff Mallinckrodt LLC, Mallinckrodt Inc., and Depomed, Inc. (herein collectively "Plaintiffs"), by their attorneys, hereby answer the Amended Counterclaims of Defendant Actavis Laboratories FL, Inc. ("Actavis"), set forth in Actavis's Amended Answer, as follows:

THE PARTIES

1. Actavis is a corporation organized under the laws of the State of Florida, having a principal place of business at 4955 Orange Drive, Fort Lauderdale, FL 33314.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1, and therefore deny them.

2. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws

of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

ANSWER: Mallinckrodt admits the allegations of paragraph 2.

3. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt Inc. is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042 2379.

ANSWER: Mallinckrodt admits the allegations of paragraph 3.

4. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Depomed, Inc. is a corporation organized and existing under the laws of the State of California, having a place of business at Gateway Blvd., Suite 300, Newark, CA 94560.

ANSWER: Depomed admits the allegations of paragraph 4.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2202.

ANSWER: Plaintiffs admit that Actavis's Counterclaims purport to arise under the Patent Laws of the United States and the Declaratory Judgment Act, but deny that Actavis is entitled to any of the requested relief.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Plaintiffs admit that this Court has subject matter jurisdiction over Actavis's counterclaims.

7. This Court has personal jurisdiction over Mallinckrodt LLC because Mallinckrodt LLC has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Mallinckrodt LLC conducts substantial business in this District.

ANSWER: Mallinckrodt admits personal jurisdiction for purposes of this action only. Mallinckrodt denies the remaining allegations of paragraph 7.

8. This Court has personal jurisdiction over Mallinckrodt Inc. because Mallinckrodt Inc. has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Mallinckrodt Inc. conducts substantial business in this District.

ANSWER: Mallinckrodt admits personal jurisdiction for purposes of this action only. Mallinckrodt denies the remaining allegations of paragraph 8.

9. This Court has personal jurisdiction over Depomed, Inc. because Depomed, Inc. has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Depomed, Inc. conducts substantial business in this District.

ANSWER: Depomed admits personal jurisdiction for purposes of this action only. Depomed denies the remaining allegations of paragraph 9.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

ANSWER: Plaintiffs admit that venue is proper in this Court for purposes of this action only.

FACTUAL BACKGROUND

11. On information and belief, and based on the FDA's website, Mallinckrodt Inc. is

the current holder of New Drug Application ("NDA") No. 204031 for the manufacture and sale of XARTEMIS XR (oxycodone hydrochloride and acetaminophen) extended-release tablets.

ANSWER: Mallinckrodt admits that it is the holder of NDA No. 204031. Mallinckrodt admits that NDA No. 204031 sought approval to market XARTEMIS XR. Mallinckrodt denies the remaining allegations of paragraph 11.

12. On information and belief, Counterclaim-defendant Mallinckrodt markets oxycodone hydrochloride and acetaminophen extended-release tablets in the United States under the trade name XARTEMIS XR. According to the FDA website, XARTEMIS XR was approved by the FDA on March 11, 2014.

ANSWER: Mallinckrodt admits the allegations of paragraph 12.

13. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt is listed as the purported owner of record and purported assignee of U.S. Patent Nos. 7,976,681 ("the '681 patent"), 8,658,631 ("the '631 patent"), 8,741,885 ("the '885 patent"), 8,980,319 ("the '319 patent"), 8,992,975 ("the '975 patent"), and 9,050,335 ("the '335 patent").

ANSWER: Mallinckrodt admits that it is the owner of record and assignee of the '681, '631, '885, '319, and '975 patents. Mallinckrodt denies the remaining allegations of paragraph 13.

14. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Depomed is listed as the purported owner and purported assignee of U.S. Patent Nos. 7,976,870 ("the '870 patent"), 8,668,929 ("the '929 patent"), 8,372,432 ("the '432 patent"), 8,377,453 ("the '453 patent"), and 8,394,408 ("the '408 patent").

ANSWER: Depomed admits that it is the owner of record and assignee of the '870, '929,

’432, and ’453 patents. Depomed denies the remaining allegation of paragraph 14.

15. Counterclaim-Defendants have informed the FDA of the unexpired ’681, ’631, ’885, ’319, ’975, ’870, ’929, ’432, ’453, ’408, and ’335 patents (collectively “the XARTEMIS XR Patents”) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of oxycodone hydrochloride and acetaminophen extended-release tablets. The XARTEMIS XR Patents are listed by the FDA in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book” for the NDA, under 21 U.S.C. § 355(j)(7).

ANSWER: Plaintiffs admit that the described XARTEMIS XR Patents are listed in the Orange Book. Plaintiffs deny the remaining allegations of paragraph 15.

16. Listing the XARTEMIS XR Patents in the Orange Book is a representation to the world that Counterclaim-Defendants believe these patents purportedly cover oxycodone hydrochloride and acetaminophen extended-release tablets, and that an infringement suit could be alleged against any generic ANDA applicant, including Counterclaim-Plaintiff, that attempts to seek approval for, and market, a generic version of oxycodone hydrochloride extended release tablets before the patents’ expiration.

ANSWER: Plaintiffs admit that the XARTEMIS XR Patents are listed in the Orange Book. Plaintiffs deny the remaining allegations of paragraph 16.

17. Actavis currently holds Abbreviated New Drug Application (“ANDA”) No. 207113 oxycodone hydrochloride and acetaminophen extended-release tablets.

ANSWER: Plaintiffs admit the allegation of paragraph 17.

18. Actavis filed certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph

IV Certification") certifying that each of the XARTEMIS XR Patents is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, importation, or sale of oxycodone hydrochloride and acetaminophen extended release tablets ("Proposed Product") as covered by ANDA No. 207113. In accordance with 35 U.S.C. § 355(j)(2)(B)(i) and (ii), Actavis sent letters to Counterclaim-Defendants that provided notice of the Paragraph IV Certifications and provided the factual and legal bases for those Certifications.

ANSWER: Plaintiffs admit that they received two letters from Actavis providing notice of Paragraph IV Certifications and purporting to provide the factual and legal bases for those Certifications. Plaintiffs deny the remaining allegations of paragraph 18.

19. In connection with the notice to Counterclaim-Defendants of Counterclaim-Plaintiff's Paragraph IV Certification, Actavis provided an offer of confidential access to its ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) and (III).

ANSWER: Plaintiffs admit that Actavis provided an offer of confidential access. Plaintiffs deny the remaining allegations of paragraph 19.

20. On June 5, 2015, Counterclaim-Defendants sued Counterclaim-Plaintiff in this district asserting infringement of the '681, '631, '885, '319, '975, '870, and '929 patents based on Actavis' filing of ANDA No. 207113 with a Paragraph IV certification. On November 2, 2015, Counterclaim-Defendants filed an amended complaint that, among other things, added allegations of infringement for the '432, '453, '408, and '335 patents. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Counterclaim-Plaintiff and Counterclaim-Defendants regarding the XARTEMIS XR Patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

ANSWER: Plaintiffs admit the allegation of paragraph 20.

21. Furthermore, based on, *inter alia*, the listing in the Orange Book of the XARTEMIS XR Patents; Actavis' filing of its ANDA with Paragraph IV Certifications to the XARTEMIS XR Patents; Actavis' intention to seek approval for its generic oxycodone hydrochloride and acetaminophen tablets before expiration of the XARTEMIS XR Patents; and Counterclaim-Defendants' suit against Counterclaim-Plaintiff for infringement of the XARTEMIS XR Patents there is a continuing case or controversy between Counterclaim-Plaintiff and Counterclaim-Defendants regarding infringement and validity of the XARTEMIS XR Patents.

ANSWER: Plaintiffs admit that a case and controversy exists related to Actavis's filing of its ANDA with Paragraph IV Certifications to the XARTEMIS Patents. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 21.

22. The Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests with regard to whether Counterclaim-Plaintiff may market and sell generic oxycodone hydrochloride and acetaminophen tablets before expiration of the XARTEMIS XR Patents.

ANSWER: Plaintiffs admit the allegations of paragraph 22.

23. Thus, Counterclaim-Plaintiff is statutorily entitled to bring and maintain this action for declaratory judgment pursuant to the Medical Modernization Act in order to obtain patent certainty, in accordance with 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

ANSWER: Plaintiffs admit that a case and controversy exists related to Actavis's filing of its ANDA with Paragraph IV Certifications to the XARTEMIS Patents. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 23.

24. As a result of any exclusion of Counterclaim-Plaintiff from the marketplace, Counterclaim-Plaintiff and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of lower-priced oxycodone hydrochloride and acetaminophen extended-release tablets.

ANSWER: Plaintiffs deny the allegations of paragraph 24.

25. This case is exceptional pursuant to 35 U.S.C. § 285 and Counterclaim-Plaintiff is entitled to its reasonable attorney fees pursuant to that statute.

ANSWER: Plaintiffs deny the allegation of paragraph 25.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '681 PATENT

26. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

27. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '681 patent.

ANSWER: Plaintiffs deny the allegation of paragraph 27.

28. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '681 patent. Therefore, a present, genuine, and justiciable

controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’681 patent.

ANSWER: Plaintiffs admit the allegation of paragraph 28.

29. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen 34 extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’681 patent.

ANSWER: Plaintiffs deny the allegation of paragraph 29.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’631 PATENT

30. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

31. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’631 patent.

ANSWER: Plaintiffs deny the allegation of paragraph 31.

32. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment

regarding the non-infringement of the ’631 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’631 patent.

ANSWER: Plaintiffs admit the allegation of paragraph 32.

33. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’631 patent.

ANSWER: Plaintiffs deny the allegation of paragraph 33.

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’885 PATENT

34. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

35. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’885 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 35.

36. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-

Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’885 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’885 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 38.

37. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’885 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 37.

FOURTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’319 PATENT

38. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

39. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’319 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 39.

40. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’319 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’319 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 40.

41. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’319 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 41.

FIFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’975 PATENT

42. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

43. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’975 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 43.

44. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’975 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’975 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 44.

45. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’975 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 45.

SIXTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’870 PATENT

46. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

47. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or

enforceable claim of the ’870 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 47.

48. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’870 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’870 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 48.

49. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’870 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 49.

SEVENTH COUNTERCLAIM DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’929 PATENT

50. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

51. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No.

207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’929 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 51.

52. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’929 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’929 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 52.

53. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’929 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 53.

EIGHTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’432 PATENT

54. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

55. The manufacture, use, sale, offer for sale, or importation of oxycodone

hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’432 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 55.

56. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’432 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’432 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 56.

57. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’432 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 57.

NINTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’453 PATENT

58. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

59. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’453 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 59.

60. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’453 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’453 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 60.

61. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’453 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 61.

TENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’408 PATENT

62. Counterclaim Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

63. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’408 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 63.

64. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’408 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’408 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 64.

65. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’408 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 65.

ELEVENTH COUNTERCLAIM OF DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’335 PATENT

66. Counterclaim Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

67. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’335 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 67.

68. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’335 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’335 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 68.

69. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’335 patent.

ANSWER: Plaintiffs deny the allegations of paragraph 69.

TWELFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’681 PATENT

70. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set

forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

71. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’681 patent.

ANSWER: Plaintiffs admits the allegations of paragraph 71.

72. One or more claims of the ’681 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 72.

73. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’681 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 73.

74. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’681 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 74.

THIRTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '631 PATENT

75. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

76. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '631 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 76.

77. One or more claims of the '631 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 77.

78. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which include the '631 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 78.

79. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’631 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 79.

FOURTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’885 PATENT

80. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

81. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’885 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 81.

82. One or more claims of the ’885 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 82.

83. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’885 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy

and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 83.

84. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’885 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 84.

FIFTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’319 PATENT

85. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

86. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’319 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 86.

87. One or more claims of the ’319 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 87.

88. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’319 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be

compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 88.

89. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’319 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 89.

SIXTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’975 PATENT

90. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

91. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’975 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 91.

92. One or more claims of the ’975 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 92.

93. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’975 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113,

Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 93.

94. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’975 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 94.

SEVENTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’870 PATENT

95. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

96. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’870 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 96.

97. One or more claims of the ’870 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 97.

98. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which include the '870 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 98.

99. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the '870 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 99.

EIGHTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '929 PATENT

100. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

101. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '929 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 101.

102. One or more claims of the '929 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not

limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 102.

103. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which include the '929 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 103.

104. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the '929 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 104.

NINETEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '432 PATENT

105. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

106. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '432 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 106.

107. One or more claims of the ’432 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and 112.

ANSWER: Plaintiffs deny the allegations of paragraph 107.

108. As a direct and proximate result of Counterclaim Defendants’ assertion of the XARTEMIS XR Patents, which are related to the ’432 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 108.

109. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’432 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 109.

TWENTIETH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’453 PATENT

110. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

111. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '453 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 111.

112. One or more claims of the '453 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 112.

113. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which are related to the '453 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 113.

114. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the '453 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 114.

TWENTY-FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '408 PATENT

115. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

116. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’408 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 116.

117. One or more claims of the ’408 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 117.

118. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which are related to the ’408 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 118.

119. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’408 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 119.

TWENTY-SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’335 PATENT

120. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of

the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

ANSWER: Plaintiffs restate and incorporate each of their responses to the preceding paragraphs as if fully set forth herein.

121. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’335 patent.

ANSWER: Plaintiffs admit the allegations of paragraph 121.

122. One or more claims of the ’335 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

ANSWER: Plaintiffs deny the allegations of paragraph 122.

123. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which are related to the ’335 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Plaintiffs deny the allegations of paragraph 123.

124. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’335 patent are invalid.

ANSWER: Plaintiffs deny the allegations of paragraph 124.

AFFIRMATIVE DEFENSE 1

The Counterclaim fails to state a claim for which relief can be granted.

AFFIRMATIVE DEFENSE 2

All allegations, averments, and claims which have not been specifically admitted are denied.

Dated: December 2, 2015

LITE DEPALMA GREENBERG, LLC

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: December 2, 2015

/s/ *Michael E. Patunas*
Michael E. Patunas

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Counterclaim-defendants hereby certifies that as a result of the nature of Counterclaim causes of action, as asserted in its counterclaims, this action is not appropriate for compulsory arbitration.

Dated: December 2, 2015

/s/ *Michael E. Patunas*
Michael E. Patunas

CERTIFICATION OF SERVICE

I hereby certify that on December 2, 2015, the foregoing RESPONSE TO ACTAVIS LABORATORIES FL, INC.'S AMENDED COUNTERCLAIMS was filed via CM/ECF with the Clerk of the Court and was thereby served on all counsel of record in this matter.

Dated: December 2, 2015

/s/ *Michael E. Patunas*
Michael E. Patunas